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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
1131-16-PCT-PA-TD

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Application Number	Filed
10/562,368	June 8, 2006

First Named Inventor	
Maurice Loretti	
Art Unit	**Examiner**
1794	Ahmed, Sheeba

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 61,941.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Brigitte C Phan
Signature

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Typed or printed name

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May 15, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _ forms are submitted.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Monique Le

Monique X. Le

Appl No.	: 10/562,368	Confirmation No. 6260
Applicant	: Maurice Loretti et al.	
Filed	: June 8, 2006	
Title	: MULTILAYER FILM	
TC/A.U.	: 1794	
Examiner	: Ahmed, Sheeba	
Docket No.	: 1135-16-PCT-PA-TD	
Customer No.	: 22145	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

43 Corporate Park, Suite 204
Irvine, CA 92606
May 15, 2009

Commissioner:

Applicant requests review of the final rejection in the above-referenced application. No amendments are being filed with this request and this request is being filed with a notice of appeal. The review is requested for the reasons stated below.

I. Inappropriate § 102(b) Rejection of Claims 1-5, 13, 17, 19, 20, 22 and 23 by Loretti

Of the rejected claims, claims 1 and 20 are independent claims. Independent claims 1 and 20 are both directed to a multilayer film comprising, among other things: (1) an outer layer with a specific range of thickness from 20 to 40 μm; (2) an oxygen transmission rate at 23°C determined by the oxygen transmission of the intermediate layer of less than 0.7ml/m^{2}d; and (3) wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C.

The '443 Loretti patent application discloses a sterilizable polymer composite tubular film having a three-layer structure: a homophase polypropylene inner layer "c)" of thickness from 60 to 100 μm, especially from 65 to 85 μm (col. 3, lines 29-33); an ethylene/vinyl alcohol

core layer "b)" of thickness from 5 to 35 μm, especially from 10 to 30 μm (col. 3, lines 9-11); and an outer layer "a)" of thickness of 40 to 100 μm, especially from 45 to 75 μm (col. 3, line 21-23).

The Examiner contends that the cited prior art anticipates the claimed multilayer film on the basis of:

1. Inherency: With regard to the above-identified properties of the claimed multilayer film, properties that are NOT disclosed or suggested in the cited reference, the Examiner takes the position that:

> ...such properties limitations are inherent in the multilayer structure taught by Loretti given that the structure of the multilayer film (i.e., the number of layers, etc.) and the chemical composition of each layer within the multilayer film [are] identical to that of the claimed multilayer film. (Page 6, final Office Action, emphasis added)

2. Anticipation of ranges: With regard to the difference in the thickness of the claimed outer layer and the referenced outer layer, the Examiner takes the position that:

> ...when the prior art discloses a range which touches or overlaps the claimed range, in order to anticipate the claims; the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." In this case, the overlapping range is taught with "sufficient specificity" given that the reference states that the outer layer should have a thickness of 40 to 100 microns" (Pages 8-9, final Office Action)

Applicant respectfully submits that the Examiner's rejection is clearly unsubstantiated.

1. With respect to inherent properties, MPEP 2112 states:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic..."**To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'** (Emphasis added).

In other words, to state that the claimed properties are inherent to the referenced multilayer film, the claimed properties should be **consistently** present for the entire disclosed thickness range, as inherency may **not** be established by probabilities or possibilities. Moreover, the prior art must disclose materials that necessarily and predictably give rise to the same claimed properties **at all times**, and not by chance or probabilities. However, nowhere in the Loretti reference is disclosed a material that can be used as an outer layer that, when used in combination with a inner layer and an intermediate layer of the claimed characteristics, produces an oxygen transmission rate at 23°C through the multilayer film of less than 0.7

ml/m^2d. The Pebax® material disclosed by Loretti when used with an inner and an intermediate layer has not been shown with high probability or consistently capable of producing the claimed characteristics. Applicant submits that there is no certainty or guarantee that a 40 to 100 μm thick outer layer will **necessarily** "allow desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121° C" resulting in "the oxygen transmission rate at 23° C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than $0.7ml/ m^2d$" **consistently** and **predictably** in the exact same way as the claimed outer layer which has a very specific and much more narrow thickness range of 20 to 40 μm. The Examiner only provided a single overlapping point as evidence of inherency. Indeed, this is the same as saying that if PVC, PTFE, UHMWPE, Teflon®, KRATON®, or any other film has the same thickness as the claimed thickness range, then it produces the same characteristics when joined with other films as claimed, which is clearly NOT the case.

In view of the foregoing, Applicant respectfully submits that the claimed properties are NOT inherent in the referenced multilayer film to the degree required by law. Reconsideration is respectfully requested.

2. With respect to anticipation of ranges, MPEP 2131.03 (II) states:

> ...In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. See, e.g., *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation. (emphasis added).

Applicant respectfully submits that contrary to the Examiner's assertion, the claimed range of 20 to 40 μm is NOT disclosed in the cited reference with "sufficient specificity". Applicant points out that in *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) cited above, despite the overlap both in the reference's broad range and preferred range with the claimed range, the court still held that the reference did not describe the claimed range with sufficient specificity for anticipation.

In this case, even though the lower limit of the referenced outer layer range overlaps with the upper limit of the claimed range, other than disclosing a broad range of 40 to 100 μm for the

outer layer, Loretti specifically teaches a preferred thickness range of "especially from 45 to 75 μm" (col. 3, line 21-23) and in the example given at paragraph [0027] specifically teaches a 50μm thick outer layer. Other than a single overlapping point of 40μm, nowhere in the cited referenced is the claimed range of 20 to 40 μm mentioned or discussed. Thus, in view of the foregoing and supported by the above-referenced case law, Applicant respectfully submits that the cited reference does NOT disclose the claimed range with "sufficient specificity" to anticipate it as required by MPEP 2131.03.

As claims 2-5, 13, 17 and 19 depend either directly or indirectly from claim 1 and claims 22 and 23 depend from claim 20, they too are allowable for at least the same reasons and allowance is respectfully solicited.

II. Lack of Prima Facie Case of Obviousness under § 103(a)

Claims 6, 18 and 21 are rejected under § 103(a) as being unpatentable over Loretti in view of Högström; claims 7-12 and 24 are rejected over Loretti in view of McKedy. The Examiner relies on Loretti to disclose the main elements and limitations disclosed in independent claims 1 and 20, on Högström to disclose a polyethylene terephthlate layer and on McKedy to disclose an oxygen absorbing composition.

Claims 6-12 depend from claim 1 and claims 21 and 24 depend from claim 20. As set forth above, Loretti fails to anticipate claim 1 and 20 under § 102(b). As Högström is merely relied on to disclose a polyethylene terephthlate layer, and McKedy is merely relied on to disclose an oxygen absorbing composition, each of those secondary references does not make up for the deficiencies of Loretti. The cited references, even if erroneously assumed combinable, still fail to disclose all the elements of independent claims 1 and 20 and thus fail to render claims 1 and 20 obvious under § 103(a). As claims 6-12 depend from claims 1 and claims 21, 24 from claim 20, they too should be allowable for at least the same reasons.

Independent claim 18 specifies a multilayer film with an outer layer comprising at least one of polyethylene terephthalate homopolymer and polyethylene terephthalate copolymer, an inner layer consisting essentially of non-polar polymeric material; and an intermediate layer having a defined ethylene content of 27 to 38 mol%.

In rejecting claim 18, the Examiner contends that Loretti teaches an inner layer and an intermediate layer as claimed and relies on Högström to disclose an outer layer made from PET or PET copolymer. (Office Action, pages 6-7).

Applicant respectfully submits that the cited references are not combinable, as Högström teaches away from using PET as an outer layer in a multilayer film that will be subjected to steam sterilization, as in the case of the claimed multilayer film, by specifically disclosing: "Polypropylene is especially preferred if the multilayer film shall be subjected to steam sterilization, but if sterilization by irradiation is for some reason desirable, polyethenes are the suitable choice for layers A and A', since polypropylenes are not sterilizable with irradiation" (Col. 5, lines 22-26). Additionally, the data presented in Table 1 (Col. 6, lines 31-66) further teach away from using PET as an outer layer to optimize the oxygen impermeability of a multilayer film, by showing superior oxygen impermeability for Film 5, which has an outer layer made of PE/polyamide relative to Film 7 which has an outer layer made of PET. Thus, Högström clearly teaches away from the instant claim. Accordingly, Högström cannot be combined with any other references to render the pending claims obvious under § 103(a), as "[i]t is improper to combine references where the references teach away from their combination. *In re Grasselli*,713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)." §MPEP 2145. Therefore, rescission of the § 103(a) rejection is respectfully solicited.

Conclusion

In view of the foregoing remarks, each of claims 1-13 and 17-24 is believed to be in condition for allowance. Early notice thereof is respectfully solicited. Should the Examiner find it necessary to speak with Applicants' agent, she is invited to contact the undersigned at the telephone number identified below.

Respectfully submitted,

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